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Image

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Cevc, et al.

Serial No: 09/890,371

Filed: April 8, 2002

Title: TRANSNASAL TRANSPORT/
IMMUNISATION WITH
HIGHLY ADAPTABLE
CARRIERS

) Examiner: Not yet assigned
)
)

) Art Unit: Not yet assigned
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) Date: October 29, 2003

) By: Patricia Munoz
Patricia Munoz

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant requests that the information on the attached Form PTO-1449 be considered by the Office during the pendency of the above-entitled application, pursuant to 37 C.F.R. 1.97. In accordance with 37 C.F.R. 1.97(h), the filing of the Information Disclosure Statement shall not constitute an admission that any information cited therein is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b). Please note that certain of these references were cited in the International Search Report on the International Preliminary Examination Report for PCT/EP00/00598 which is the PCT application upon which this United States National filing is


based. In the interest of full and complete disclosure to the Office, some or all of the art cited herein may not be considered by Applicant(s) or the Undersigned to be material under the standards of materiality defined in C.F.R. 1.56(b), enacted March 16, 1992, as amended September 8, 2000, and may merely be technical background which may be of interest to the Examiner.

In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

Since no Office Action has issued, Applicants believe that no fee is due in connection with the filing of this Information Disclosure Statement. However, please charge any fees that may be necessary to Deposit Account No. 50-2212, Order No. 009848-0272496.

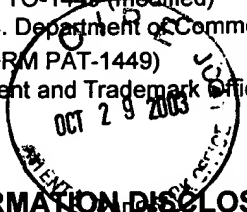
Respectfully submitted,

Date: October 29, 2003


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FORM PTO-1449 (modified)
To: U.S. Department of Commerce
(PW FORM PAT-1449)
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Client Ref.

009848-0272496

C2481/US

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Applicant: Cevc, et al.

Appln. No.: 09/890,371

Filing Date: April 8, 2002

Examiner: Not yet assigned

Group Art Unit: Not yet assigned

Date: October 29, 2003

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U.S. PATENT DOCUMENTS

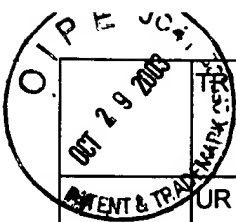
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FOREIGN PATENT DOCUMENTS

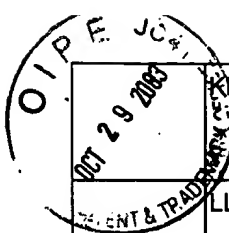
		Document Number	Date MM/YYYY	Country	Inventor Name	English Abstract		Translation Readily Available	
						Enclosed	No	Enclose	No
	BR	DE 41 07 152	09/1992	DE	Cevc, G.				
	CR	DE 44 47 287	11/1996	DE	Cevc, G.				
	DR	EP 0 475 160 A1	08/1991	EP	Cevc, G.				
	ER	EP 0 475 160 B1	08/1991	EP	Cevc, G.				
	FR	WO 90/09385	08/1990	WO	Weiner, A.L.				
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	JR	WO 00/24377	05/1998	WO	Cevc, G.				
	KR								

OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)

LR	Almeida, A.J., et al., Nasal delivery of vaccines, J. Drug Targeting, 3:455-467 (1996)			
MR	Bagnasco, M. et al, Absorption and distribution kinetics of the major Parietaria judaica allergen (Par j 1) administered by noninjectable routes in healthy human beings, J.Allergy Clin. Immunol (1997) 100: 122-9			
NR	Biberoglu, K., et al., Treatment of estrogen-dependent gynecological disorders with the gonadotropin releasing hormone agonist buserelin, Gynecol. Endocrinol. 1991; 5: 109-22			
OR	Bruins, J., et al., Effect of acute and chronic treatment with desglycinamide-[Arg ⁸]Vasopressin in young male and female volunteers. Peptides, 1995; 16: 179-86			
PR	Cevc, G., et al., Drug delivery across the skin, Exp. Opin. Invest. Drugs (1997) 6: 1887-1937			
QR	Cevc, G., Transfersomes, liposomes and other lipid suspensions on the skin: Permeation enhancement, vesicle penetration, and transdermal drug delivery, Critical Reviews in Therapeutic Drug Carrier Systems, 13(3&4):257-388 (1996)			
RR	Cevc, G., et al., Ultraflexible vesicles, transfersomes, have an extremely low permeation resistance and transport therapeutic amounts of insulin across the intact mammalian skin. Biochim. Biophys. Acta 1998; 1368: 201-215			
SR	Draghia, R., et al., Gene delivery into the central nervous system by nasal instillation in rats. Gene-Ther. 1995; 2: 418-23			



TER	Drejer, K., et al., Intranasal administration of insulin with phospholipid as absorption enhancer: pharmacokinetics in normal subjects, Diab. Med. 1992, 9:335-340.				
UR	Flanagan, B., et al., A recombinant human adenovirus expressing the simian immunodeficiency virus Gag antigen can induce long-lived immune responses in mice, J. Gen. Virol. 1997; 78: 991-7				
VR	Gizurason, S., et al., Intranasal administration of insulin to humans. Diabetes Res. Clin. Pract. 1991 May; 12: 71-84				
WR	Ghigo, E.; et al., Short-term administration of intranasal or oral Hexarelin, a synthetic hexapeptide, does not desensitize the growth hormone responsiveness in human aging. Eur. J. Endocrinol. 1996; 135: 407-12				
XR	Harris, AS, Review: clinical opportunities provided by the nasal administration of peptides. J. Drug Target. 1993; 1: 101-16				
YR	Huneycutt, BS, et al., Distribution of vesicular stomatitis virus proteins in the brains of BALB/c mice following intranasal inoculation: an immunohistochemical analysis, Brain Res. 1994; 635: 81-95				
ZR	Hussain A., et al., Does increasing the lipophilicity of peptides enhance their nasal absorption? J. Pharm. Sci. 1991; 80: 11 80-1				
AAR	Ichikawa-M, et al., Anti-osteopenic effect of nasal salmon calcitonin in type 1 osteoporotic rats: comparison with subcutaneous dosing, Biol. Pharm. Bull. 1994; 17: 911-13				
BBR	Illum, L., The nasal delivery of peptides and proteins. Trends Biotechnol. 1991; 9: 284-9				
CCR	Illum, L.; et al., Intranasal insulin. Clinical pharmacokinetics. Clin. Pharmacokinet. 1992 Jul; 23: 30-41				
DDR	Invitti, C., et al., Effect of chronic treatment with octreotide nasal powder on serum levels of growth hormone, insulin-like growth factor I, insulin-like growth factor binding proteins 1 and 3 in acromegalic patients, J. Endocrinol. Invest. 1996; 19: 548-55				
EER	Kida, S., et al., CSF drains directly from the subarachnoid space into nasal lymphatics in the rat. Anatomy, histology and immunological significance. Neuropathol. Appl. Neurobiol. 1993; 19: 480-448				
FFR	Laursen, T., et al., Bioavailability and bioactivity of three different doses of nasal growth hormone (GH) administered to GH-deficient patients: comparison with intravenous and subcutaneous administration, Eur. J. Endocrinol. 1996; 135: 309-15				
GGR	Machida, M., et al., Absorption of recombinant human granulocyte colony-stimulating factor (rhG-CSF) from rat nasal mucosa, Pharm. Res. 1993; 10(9): 1372-7.				
HHR	Maejima, K.; et al., Comparison of the effects of various fine particles on IgE antibody production in mice inhaling Japanese cedar pollen allergens. J. Toxicol. Environ. Health. 1997; 52: 231 -48				
IIR	Maitani, Y., et al., Influence of molecular weight and charge on nasal absorption of dextran and DEAE-dextran in rabbits, Int'l. J. Pharmaceut. 1989; 49: 23-27				
JJR	McMartin, C., et al., Analysis of structural requirements for the absorption of drugs and macromolecules from the nasal cavity, J. Pharm. Sci. 1987; 76: 535-540				



KKR	Mori, I., et al., Temperature-sensitive parainfluenza type 1 vaccine virus directly accesses the central nervous system by infecting olfactory neurons. J. Gen. Virol. 1996; 77: 2121-4				
LLR	Naumann, E., et al., Vasopressin and cognitive processes: two event-related potential studies. Peptides. 1991; 12: 1379-84				
MMR	Pasechnik, V., et al., Macromolecular drug delivery to the CNS with protein carriers. Exp. Opin. Invest. Drugs 1996, 5:1255-1276				
NNR	Paul, A., et al., Non-invasive Administration of Protein Antigens: Transdermal Immunization with Bovine Serum Albumine in Transfersomes. Vaccine Res. 1995; 4(3):145-164				
OOR	Perras, B., et al., Sleep and signs of attention during 3 months of intranasal vasopressin: a pilot study in two elderly subjects. Peptides. 1996; 17: 1253-55				
PPR	Pietrowsky, R., et al., Brain potential changes after intranasal vs. intravenous administration of vasopressin: Evidence for a direct nose- brain pathway for peptide effects in humans. Biol. Psychiatry. 1996; 39: 332-40				
QQR	Pihoker, C., et al., Diagnostic studies with intravenous and intranasal growth hormone-releasing peptide-2 in children of short stature. J. Clin. Endocrinol. Metab. 1995; 80(10): 2987-92				
RRR	Pohl, J., et al., Modulation of pain perception in man by a vasopressin analogue. Peptides. 1996; 17: 641-7				
SSR	Sarkar, MA, Drug metabolism in the nasal mucosa. Pharm-Res. 1992; 9: 1-9				
TTR	Shimoda, N., et al., Effects of dose, pH and osmolarity on intranasal absorption of recombinant human erythropoietin in rats, Biol. Pharm. Bull. 1995; 18(5): 734-9				
UUR	Sperber, S.J., et al., Otologic effects of interferon beta serine in experimental rhinovirus colds, Arch. Otolaryngol. Head. Neck. Surg. 1992; 118: 933-6				
VVR	Ting, T.Y., et al., Microparticles of polyvinyl alcohol for nasal delivery. I. Generation by spray-drying and spray-desolvation, Pharm. Res. 1992; 9: 1330-5				
WWR	Tsume, Y, et al., Quantitative evaluation of the gastrointestinal absorption of protein into the blood and lymph circulation, Biol. Pharm. Bull. 1996; 19(10): 1332-1337				
XXR	Watanabe, Y., et al., Absorption of recombinant human granulocyte colony-stimulating factor (rhG-CSF) and blood leukocyte dynamics following intranasal administration in rabbits, Biol. Pharm. Bull. 1993; 16: 93-5				
YYR	Watanabe, Y., et al., Pharmacokinetics and pharmacodynamics of recombinant human granulocyte colony-stimulating factor (rhG-CSF) following intranasal administration in rabbits, J. Drug Target. 1995; 3: 231-38				
ZZR	Wearley, L.L., Recent progress in protein and peptide delivery by noninvasive routes, Crit. Rev. Ther. Drug Carrier Syst. 1991; 8: 331-94				
AAAR	Westenberg, H.G., et al., Pharmacokinetics of DGAVP in plasma following intranasal and oral administration to healthy subjects, Peptides, 1994; 15: 1101-4				
BBBR	Van der Wiel, H.E., et al., Intranasal calcitonin suppresses increased bone resorption during short-term immobilization: A double-blind study of the effects of intranasal calcitonin on biochemical parameters of bone turnover. J. Bone Mineral Res. 1993; 8:1459-65				

Examiner

Date Considered:

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.